

PREPUBLICATION COPY NOTICE:

The Acting Assistant Administrator for Chemical Safety and Pollution Prevention signed the attached proposed rule on March 30, 2012.

This is a prepublication version of the proposed rule that EPA is submitting for publication in the *Federal Register*. While the Agency has taken steps to ensure the accuracy of this prepublication version of the document, it is not the official version of the document for purposes of public comment or judicial review. Please refer to the official version of the document that will appear in a forthcoming *Federal Register* publication.

Once the official version of the document publishes in the *Federal Register*, the advance publication version of the document posted on the internet will be replaced with a link to the document that published in the *Federal Register*. At that time, you will also be able to access the on-line docket for this proposed rule at <http://www.regulations.gov> under **Docket ID# EPA-HQ-OPPT-2011-0519**. You can then use EPA's electronic docket and comment system at <http://www.regulations.gov>, to access the index listing of the contents of the docket, to submit or view public comments, and to access those documents in the docket that are available electronically. For further information about the docket and commenting, please consult the ADDRESSES section in the front of the proposed rule.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 712, 716, 720, 721, 723, 725, 766, 790, and 799

[EPA-HQ-OPPT-2011-0519; FRL-9337-5]

RIN 2070-AJ75

Electronic Reporting Under the Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to require electronic reporting for information that must be submitted under Toxic Substances Control Act (TSCA) section 4 (pursuant to test rules and enforceable consent agreements (ECAs)), TSCA section 8(a) Preliminary Assessment Information Rule (PAIR), and TSCA section 8(d) Health and Safety Data Reporting rules. Additionally, EPA is proposing amendments to certain TSCA section 5 reporting regulations that would extend electronic reporting requirements to Notices of Commencement of Manufacture or Import (NOCs) and support documents (e.g., correspondence, amendment, and test data) relating to TSCA section 5 notices submitted to EPA before April 6, 2010. This proposed rule would require the use of EPA's Central Data Exchange (CDX) and the Chemical Information Submission System (CISS) web-based reporting tool for the submission of forms, reports, and other documents except for TSCA section 5 submissions, which would use existing e-PMN software. This action is intended to streamline the reporting process and reduce the administrative costs associated with information submission and recordkeeping.

DATES: Comments must be received on or before [*insert 60 days after date of publication in the Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2011-0519, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2011-0519. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2011-0519. EPA's policy is that all comments received will be included in the docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If

you send an email comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Katherine Sleasman, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-7716; email address: *sleasman.katherine@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture (including import), process, or distribute in commerce chemical substances and mixtures. Potentially affected entities may include, but are not limited to:

- Chemicals and Allied Products Manufacturers (NAICS 32411).
- Petroleum Refining (NAICS Codes 325 and 32411).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

The Agency is proposing regulations to require electronic reporting of information submitted under TSCA section 4 (including test rules and ECAs), TSCA section 8(a) PAIR rule at 40 CFR part 712, and TSCA section 8(d) Health and Safety Data Reporting rules to require use of CISS, a web-based reporting tool.

The Agency is also proposing to extend TSCA section 5 electronic reporting requirements to NOCs and support documents (e.g., correspondence, amendments, and test data) relating to TSCA section 5 notices submitted to EPA prior to April 6, 2010, the effective date of the e-PMN final rule (Ref. 1). Currently, follow-up submissions for TSCA section 5 notices submitted before this date are not subject to electronic reporting requirements.

The Government Paperwork Elimination Act (GPEA) (44 U.S.C. 3504) provides that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public. EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (40 CFR part 3) (Ref. 2), provides that any requirement in title 40 of the CFR to submit a report directly to EPA can be satisfied with an electronic submission that meets certain conditions once the Agency published a document in the **Federal Register** announcing that EPA is prepared to receive certain documents in electronic form. For more information about CROMERR, go to <http://www.epa.gov/cromerr>.

This action would require electronic reporting under TSCA section 4 test rules and ECAs, TSCA section 8(a) PAIR, TSCA section 8(d) regulations, and TSCA section 5-related reporting provisions where electronic reporting is not already required, taking into consideration the

frequency of reporting under these regulations. EPA is considering undertaking additional rulemaking regarding requiring electronic reporting for other TSCA requirements that currently include paper-reporting obligations. Once this proposed rule becomes effective, EPA would accept only data, reports, and other information submitted through CDX. Data, reports, and other information not submitted in the manner required would be considered invalid by EPA. In addition, the Agency encourages that voluntary submissions, such as those under Memoranda of Understandings (MOUs), also be submitted through CDX. The following regulations would be affected:

1. *TSCA section 4 test rules and ECAs.* Documents required under TSCA section 4, include but are not limited to, letters of intent to conduct testing (40 CFR 790.45), extension requests (40 CFR 790.50), modification requests (40 CFR 790.55), exemption requests (40 CFR 790.80 and 40 CFR 790.82), hearing requests (40 CFR 790.90), and data required to be developed under rules at 40 CFR part 799, and documents and correspondence related to ECAs negotiated pursuant to 40 CFR part 790. Affected sections would include those relating to submission or modification of a study plan (40 CFR 790.62), and requests to modify the test schedule for any test required under the consent agreement (40 CFR 790.68). Electronic reporting requirements for TSCA section 4 rules and ECAs would be added to 40 CFR 766.7, 790.5, and 799.50.

2. *TSCA section 5.* Additionally, EPA is proposing amendments to certain TSCA section 5 reporting regulations that would extend electronic reporting requirements to NOCs and support documents (e.g., correspondence, amendment, and test data) relating to TSCA section 5 notices submitted to EPA before April 6, 2010. The e-PMN final rule (Ref. 1) requires submitters of NOCs and support documents whose original notices were submitted to EPA prior

to April 6, 2010 (“legacy notices”) to submit those NOCs and support documents to EPA in hard copy. At the time the final rule was published, EPA believed the hard-copy submission of these documents was necessary because the Agency intended to operate two different databases; one for storing TSCA section 5 notices submitted to EPA after April 6, 2010, and another for storing legacy notices. EPA originally intended to enter legacy notices only into EPA’s “legacy database,” i.e., the database used prior to April 6, 2010, and so a subsequent NOC or support document would not have been able to be linked up with its original or “parent” legacy notice if it was entered into EPA’s new database.

However, since publication of the e-PMN final rule, EPA’s electronic reporting program has evolved and EPA now has the ability to house both legacy notices and notices submitted after April 6, 2010, in the same database. EPA is therefore proposing to amend the regulations at 40 CFR parts 720, 721, 723, and 725 to require NOCs and support documents for TSCA section 5 notices originally submitted prior to April 6, 2010, to be submitted electronically allowing them to be stored with their legacy TSCA section 5 notices in the new database.

Within the e-PMN final rule, EPA phased-in electronic reporting of TSCA section 5 notices and their related NOCs and support documents over a 2-year period that ends April 6, 2012. Within this proposed rule, EPA would remove the regulatory text related to the phase-in because by the time this proposed rule is finalized, EPA expects the phase-in period will be over and all TSCA section 5 notices, NOCs, and support documents would be required to be submitted to EPA via CDX.

3. *TSCA section 8(a) PAIR*. Electronic reporting requirements for Form 7710-35, Manufacturer's Report--Preliminary Assessment Information (Manufacturer’s Report) would be included in 40 CFR 712.28 and 712.30.

4. *TSCA section 8(d)*. The submission of data, reports, and other documents are required under the TSCA section 8(d) Health and Safety Data reporting rule at 40 CFR part 716 and the Dibenzo-para-dioxins/Dibenzofurans rule at 40 CFR part 766 (specifically 40 CFR 716.30, 716.35, 716.60, and 766.7). Additional affected sections of 40 CFR part 716 would include: The submission of underlying data, preliminary reports of ongoing studies, additional copies of studies (40 CFR 716.40), requests for extension of time (40 CFR 716.60), and requests for withdrawal of a chemical substance from a rule (40 CFR 716.105).

B. What is the Agency's Authority for Taking this Action?

The Agency collects information from manufacturers and processors of chemical substances under TSCA section 4 regulations, TSCA section 8(a) PAIR, and TSCA section 8(d) regulations. Section 4 of TSCA authorizes EPA to require manufacturers and processors of chemical substances and mixtures to perform testing to generate data relevant to a determination whether the manufacture, distribution in commerce, processing, use, or disposal of such chemical or mixtures presents an unreasonable risk of injury to health or the environment. Some TSCA section 4 testing data are required via ECAs. Section 8(a) of TSCA gives EPA authority to promulgate rules to require that manufacturers (includes importers) and processors of chemical substances and mixtures report such data as EPA may reasonably require. One TSCA section 8(a) reporting rule is the PAIR at 40 CFR part 712. The PAIR requires chemical manufacturers and importers to complete and submit to EPA a standardized reporting form with information to help facilitate the evaluation of the potential adverse human health and environmental effects from exposure to identified chemical substances, mixtures, or categories. Under TSCA section 8(d), EPA has the authority to promulgate rules to require manufacturers (including importers),

processors, and distributors to submit lists and/or copies of ongoing and completed unpublished health and safety studies.

Section 5(a)(1)(A) of TSCA requires persons to notify EPA at least 90 days before manufacturing a new chemical substance for commercial purposes (under TSCA manufacture includes import). Section 3(9) of TSCA defines a “new chemical substance” as any chemical substance that is not on the TSCA Inventory of Chemical Substances compiled by EPA under TSCA section 8(b). Section 5(a)(2) of TSCA authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by a Significant New Use Rule (SNUR) after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a Significant New Use Notice (SNUN) to EPA at least 90 days before manufacturing or processing the chemical substance for that use.

C. Is Electronic Reporting Currently Required in Other EPA TSCA Programs?

Since 2006, under the TSCA section 8(a) Inventory Update Reporting rule (IUR), manufacturers (including importers) have been able to submit IUR information electronically to the EPA through CDX (Ref. 3). EPA is improving upon the 2006 IUR electronic reporting software by making electronic reporting easier and more accessible to potential reporters, including non-U.S. companies and those submitters filing jointly. On August 16, 2011 (Ref. 4), the Agency published the final Chemical Data Reporting (CDR) rule, amending and renaming the IUR rule and making electronic reporting mandatory, beginning with the 2012 submission period. In addition, on January 6, 2010, EPA published the e-PMN final rule, which phased in electronic reporting requirements for TSCA section 5 notices and other related documents over a

2-year period. After the 2-year phase-in period ends on April 6, 2012, the final rule mandates electronic reporting for these documents (Ref. 1).

III. Description of Proposed Changes to Reporting Procedures

This unit provides an overview of EPA's CDX, CISS, and e-PMN software for NOCs and support documents associated with legacy TSCA section 5 notices, the proposed changes to the TSCA reporting process, and the benefits of electronic reporting to both industry and EPA.

A. What is CDX?

CDX is EPA's electronic system for environmental data exchange to the Agency. CDX also provides the capability for submitters to access their data through the use of web services. CDX enables EPA to work with stakeholders, including governments, regulated industries, and the public to enable streamlined, electronic submission of data via the Internet. For more information about CDX, go to <http://epa.gov/cdx>.

B. What is CISS?

EPA developed CISS for use in submitting data for TSCA sections 4, 8(a), and 8(d) electronically to the Agency. The tool is available for use with Windows, Macs, Linux, and UNIX based computers, using "Extensible Markup Language" (XML) specifications for efficient data transmission across the Internet. CISS, a web-based reporting tool, provides user-friendly navigation, works with CDX to secure online communication, creates a completed Portable Document Format (PDF) for review prior to submission, and enables data, reports, and other information to be submitted easily as PDF attachments, or by other electronic standards, such as XML.

C. What is the e-PMN Software for TSCA Section 5?

EPA developed e-PMN software for use in preparing and submitting Premanufacture Notices (PMNs) and other TSCA section 5 notices and support documents electronically to the Agency. For further information on the software capabilities, please visit the TSCA New Chemicals Program website <http://www.epa.gov/oppt/newchems>. Also, see the e-PMN final rule for further guidance (Ref. 1).

D. What are the Benefits of CDX Reporting and Use of CISS and the e-PMN Software?

The effort to eliminate paper-based submissions in favor of CDX reporting, including use of CISS, is part of broader government efforts to move to modern, electronic methods of information gathering. CISS and e-PMN software enable more efficient data transmittal and reduce errors with the built-in validation procedures. EPA believes the adoption of electronic reporting reduces the reporting burden for submitters by reducing the cost and time required to review, edit, and transmit data to the Agency. It also allows submitters to share a draft submission within their organization, and more easily save a copy for their records or future use. The resource and time requirements to review and process data by the Agency will also be reduced and document storage and retrieval will require fewer resources. EPA expects to benefit from receiving electronic submissions and communicating back electronically with submitters. In addition, the use of CDX, CISS, and e-PMN software ensures the legal dependability of electronic reports so that they meet the needs of the compliance and enforcement programs. The legal dependability of electronically submitted documents is enhanced by valid electronic signatures that can be submitted into evidence, assurance that electronic documents can be authenticated to provide evidence of what an individual submitted and/or attested to, and assurance that electronic signatures resist repudiation by the signatory (Ref. 5).

E. How Would Data, Reports, and Other Documents Required Under TSCA Sections 4, 8(a) PAIR, and 8(d) be Submitted via the Internet Using CDX?

This proposed rule would require submitters to register with EPA's CDX and use CISS to prepare a data file for submission.

1. *Registering with CDX.* Registration enables CDX to perform two important functions:

- i. Authentication of identity.
- ii. Verification of authorization.

To submit electronically to EPA via CDX, individuals must first register with that system at http://cdx.epa.gov/epa_home.asp.

To register in CDX, the CDX registrant (also referred to as "Electronic Signature Holder" or "Public/Private Key Holder") agrees to the Terms and Conditions, provides information about the submitter and organization, selects a user name and password, and follows the procedures outlined in the guidance document for CDX available at http://www.epa.gov/cdr/tools/CDX_Registration_Guide_v0_02.pdf.

User who have previously registered with CDX for TSCA section 5 submissions, or the Toxic Release Inventory TRI-ME web reporting flow, will be able to add the "Submission for Chemical Safety and Pesticide Program (CSPP)" CDX flow to their current registration, and use the CISS web-based reporting tool.

2. *Preparing the submission.* All submitters would be required to use CISS to prepare their submissions. CISS guides users through a "hands-on" process of creating an electronic submission. Once a user completes the relevant data fields, attaches appropriate PDF files, or other file types, such as XML files, and completes metadata information, the web-based tool validates the submission by performing a basic error check and makes sure all the required fields and attachments are provided and complete. Further instructions on submitting voluntary

submissions, such as under MOUs, are available, and instructions for uploading PDF attachments or other file types, such as XML, and completing metadata information would be available through CISS reporting guidance.

3. *Completing the submission to EPA.* CISS, a web-based reporting tool, also allows the user to choose “Print,” “Save,” or “Transmit through CDX.” When “Transmission through CDX” is selected, the user is asked to provide the user name and password that was created during the CDX registration process. CISS then encrypts the file and submits it via CDX.

4. *Correspondence through CDX.* The user will login to the application and check the status of their submissions. Upon successful receipt of the submission by EPA, the status of the submissions will be flagged as “Completed.” The CDX inbox is currently used to notify the users of any correspondence related to user registration. Information on accessing the CDX user inbox is provided in the guidance document for CDX at

http://www.epa.gov/cdr/tools/CDX_Registration_Guide_v0_02.pdf.

F. How Would TSCA Section 5 NOCs and Support Documents Relating to Legacy TSCA Section 5 Notices be Submitted to EPA?

EPA is proposing that NOCs and support documents relating to legacy TSCA section 5 notices be submitted to EPA using the same process and timeline as described in 40 CFR 720.40(a)(2), see Unit II.A.3. All NOCs and support documents would be required to be generated using e-PMN software and be completed through the finalization step of the software. See the e-PMN final rule (Ref. 1) for more detailed information on the process and timeline for submitting NOCs and support documents.

G. How Would CBI be Submitted Using CISS?

All information sent by the submitter via CDX is transmitted securely to protect CBI. CISS enables the user to submit CBI in an electronic format. The reporting tool guides the user

through the process of submitting CBI by prompting the submitter to check a CBI checkbox if using a form or by submitting a scanned document containing CBI by bracketing, underlining, or otherwise marking the confidential information on the document to be submitted prior to scanning. Documents containing information claimed as CBI would have to be submitted in an electronic format, in accordance with the recordkeeping requirements (Ref. 5) and the following regulations:

1. *TSCA section 4 test rules and ECAs.* Documents required under TSCA section 4 that may contain information claimed as CBI include study plans submitted in accordance with test rules (40 CFR 790.50) and study plans submitted in accordance with an ECA (40 CFR 790.62). CISS would allow the submitter to indicate if a study plan contains information claimed as CBI by checking the appropriate box. Then, the submitter would be prompted to submit the study plan document in an electronic format. The submitter would need to indicate which information in the study plan contains information claimed as CBI by marking the specific information claimed as confidential and designating it with the words “confidential business information,” “trade secret,” or another appropriate phrase in the document prior to scanning. Subsequently, if CBI is claimed in either a study plan for test rules or an ECA, the submitter would be prompted by CISS to substantiate those claims by answering the substantiating questions pursuant to 40 CFR 790.7 in a document submitted in an electronic format.

2. *TSCA section 8(a) PAIR.* CISS would include areas for indicating CBI on Form 7710-35, Manufacturer’s Report, (40 CFR 712.28 and 712.30). If CBI is indicated on Form 7710-35, the reporting tool would prompt the submitter to certify that the confidentially statements are true by prompting the submitter to select the “Confidentiality Certification Statement.”

3. *TSCA section 8(d)*. Documents submitted under TSCA section 8(d) that contain information claimed as CBI would have to be indicated as such by using CISS. CISS would allow the submitter to indicate if the document contains CBI by checking the appropriate box. Then, the submitter would be prompted to submit the document in an electronic format. In submitting a document that contains CBI, CISS would prompt the submitter to submit two copies of the document in an electronic format. The copy containing CBI would need to identify the confidential information by bracketing or underlining the information and labeling the copy “confidential,” “proprietary,” or “trade secret.” The non-CBI second copy would need to have all confidential information deleted. Once CBI is claimed, CISS would prompt the submitter to substantiate their claims (40 CFR 716.55).

The user guide would also instruct users on how to submit and substantiate CBI information using CISS.

H. Would CBI be Protected When Submitting via CDX?

All information sent by the submitter via CDX would be transmitted securely to protect CBI. Furthermore, if anything in the submission is claimed as CBI, a non-CBI copy of the submission would have to be provided by the submitter. The guidance document would instruct users on how to submit and substantiate CBI information using CISS.

The Agency ensures secure transmission of the data, reports, and other documents sent from the user's desktop through the Internet via the Transport Layer Security (TLS) 1.0 protocol. TLS 1.0 is a widely used approach for securing Internet transactions and is endorsed by the National Institute of Standards and Technology (NIST) as a means for protecting data sent over the Internet. See NIST Special Publication 800-52, “Guidelines for the Selection and Use of

Transport Layer Security (TLS) Implementations.” Available online at <http://csrc.nist.gov/publications/nistpubs/800-52/SP800-52.pdf>.

In addition, CISS enables the submitter to electronically sign, encrypt, and transmit submissions which EPA subsequently provides back to the submitter as an unaltered copy of record. This assures the submitter that the Agency has received exactly what the submitter sent to EPA. CISS encrypts using a module based on the 256-bit Advanced Encryption Standard (AES) adopted by NIST. Details about AES can be found on the NIST website at <http://csrc.nist.gov/publications/fips/fips197/fips-197.pdf>, and EPA may incorporate other encryption modules into future versions of the tool (such versions might be developed before or after the final rule is to take effect depending upon availability and suitability). Information submitted via CDX is processed within EPA by secure systems certified for compliance with Federal Information Processing Standards.

I. Would EPA Offer Any Exceptions to the Proposed Requirements?

The Agency does not expect to offer any exceptions to any final requirements to submit data, reports, and other documents affected by this proposed rule electronically. The Agency believes that the overall benefits of using CISS and e-PMN software, and submission through CDX exceed those associated with maintaining a paper-based reporting approach. The proposed electronic reporting requirements are not the first that would mandate electronic reporting as explained in Unit II.C. For example, the e-PMN final rule provided for a phased-in approach using CDX in three phases over a 2-year period. During the first year following the April 6, 2010 effective date of the final rule, the Agency allowed submissions via CDX, optical disc (CD or DVD), and paper. Paper submissions are no longer accepted, and optical discs will no longer

be accepted after April 6, 2012. The phased-in approach was designed to allow submitters to gain experience using the e-PMN software and the submission delivery system (Ref. 6).

On August 16, 2011, the Agency published the final rule for the TSCA Inventory Update Reporting Modifications; Chemical Data Rule (Ref. 4). This final rule requires electronic reporting and does not provide for a phased-in approach. Previously, in 2006 EPA accepted the 2006 IUR submissions electronically via CDX, optical discs, and paper-based methods. However, by allowing submissions to be received through a variety of mechanisms, the time and resources needed to review and correct submitter and scanning-related errors took the Agency over 2 years to validate and process for the 2006 IUR. By requiring submissions to be sent via CDX and the e-CDR web-based reporting tool, called e-CDRweb, resources and the number of errors should be greatly reduced.

The Agency recognizes that there is the potential for costs and burdens associated with predictable or unanticipated technical difficulties in electronic filing or with conversion to an electronic format. Since the use of CDX has been in existence for a number of years and has undergone a number of enhancements, EPA expects the potential for difficulty to be minimal. However, EPA expects that reduced reporting costs to submitters would ultimately exceed the transition costs (see Economic Analysis referenced in Unit IV.).

J. How Will the Agency Provide Opportunities for Potential Users to Become Familiar With the Reporting Tool?

The Agency will offer a webinar open to the public for potential users to become familiar with CISS before its release following publication of the final rule. The webinar will be recorded and available at <http://www.epa.gov/oppt/chemtest/ereporting/index.html>. An “Industry Day” will be scheduled to allow users to become familiar with CISS in a collaborative setting. Industry Day details will be announced in the **Federal Register**. There will also be a week-long

familiarization opportunity to allow users to become accustomed with CISS on their own and to provide comments to the Agency on its functionality.

IV. Economic Analysis

The Agency's estimated economic impact of this proposed rule is presented in a document entitled "Economic Analysis for the Electronic Reporting under TSCA Section 4, Section 5 NOCs, Section 8(a) PAIR, and Section 8(d)" (Ref. 7) (Economic Analysis), a copy of which is available in the docket and is briefly summarized in this unit. If a TSCA section 5 PMN or a SNUN was submitted after the effective date (April 6, 2010) of the e-PMN final rule it would be subject to the e-PMN final rule and is required to be submitted electronically online. However, if a TSCA section 5 PMN or SNUN was submitted prior to the effective date of the e-PMN final rule (April 2010), it must be printed and mailed as hard copy to the Agency. This proposed rule would require all NOC and supporting documents whose original notices were submitted on paper before the new system was implemented to now be submitted electronically via the CDX system.

EPA estimated that this proposed rule, if finalized, would result in cost savings to the affected companies because the time required to enter, review, edit, and submit their reports using CDX would be reduced compared to the existing paper-based process.

EPA estimated that this proposed rule would result in total cost to the industry of approximately \$14,061 in year 1 and a cost savings of \$66,834 in each subsequent year. The cost savings in subsequent years are greater than those in year 1 because of the one-time CDX registration costs incurred at the initial submission. EPA assumed that industry would continue to realize cost savings each additional year.

EPA estimates that the Agency also would experience a reduction in the cost to administer submissions of data under TSCA in the long-run. Due to the one-time development cost of \$200,000 for CDX in year 1 and an annual CDX Operations and Maintenance (O&M) cost of \$57,353, EPA would incur a cost of \$197,918 in year 1, after accounting for \$59,435 in savings resulting from the burden reductions associated with electronic processing of submissions within the Agency. However, in subsequent years, EPA would only incur the \$57,353 annually in O&M costs, resulting in the Agency savings of \$2,082 a year in subsequent years.

In addition to the quantifiable cost savings, EPA believes this proposed rule would result in other benefits. For example, electronic reporting would allow for faster review and transmission of submissions to EPA. For studies containing CBI, electronic reporting would also improve security during transmission of CBI data to EPA. Additionally, all information submitted electronically could be linked in a tracking system, which would facilitate document management efforts. This would allow companies to manage past and future submissions more easily.

EPA received 9,280 TSCA section 5 supporting documents between April 1, 2005 and June 22, 2011, with an average of 1,510 supporting documents each year. EPA assumed that the impact of this proposed rule on TSCA section 5 supporting documents would be very minimal given that industry has already undertaken electronic submission of such supplemental materials.

V. Request for Comment

The Agency is specifically soliciting comments on the following five topics. EPA encourages all interested persons to submit comments on these five topics or other relevant topics and submission of data via CDX. This input will assist the Agency in developing a final

rule that addresses information needs while minimizing reporting burdens associated with paper-based reporting. EPA requests that comments include specific recommendations, where appropriate, including cost and burden estimates.

1. EPA expects that reporting health and safety information electronically would reduce the burden associated with current paper-based submission method under TSCA. EPA is seeking information that might further inform the Agency's burden estimates. Estimated costs presented by EPA for submitters (reporting burden) and the Agency (time required for manual processing of data) may overstate actual costs to the extent that submitters are able to use the electronic submission tool. EPA invites comment on the relative time and resource burden of completing CDX registration requirements and making an electronic submission, versus making a submission via the current paper-based method.

2. EPA seeks comment on its belief that persons required to report information under TSCA section 4 or 8(d) rules, or under the TSCA 8(a) PAIR would benefit from moving from paper based reporting to electronic because it is less expensive, faster, and easier.

3. CISS enables submitters to send CBI electronically. EPA invites comments on the submission of CBI information via CDX. The Agency is requesting submitters use a Portable Document Format (PDF) to send documents to the Agency. Would this be an acceptable format for submitters to send CBI to the Agency or is there another format submitters would prefer?

4. EPA is also considering using CDX to send correspondence relating to submissions under TSCA sections 4 and 8(d) rules. EPA invites comments on whether persons required to report under these sections of TSCA would benefit from receiving electronic correspondence from EPA via CDX.

5. CISS allows submitters to provide some information to EPA in fielded formats, such as the chemical identity, while also allowing submitters to upload files as attachments to a web-based form. EPA invites comments on the submission of forms, reports, and other documents in fielded formats. Would it be feasible for submitters to enter data and information in a fielded format, e.g., the Organisation for Economic Co-operation and Development (OECD) harmonized template formats? The OECD harmonized template formats are available online at:

http://www.oecd.org/document/18/0,3746,en_21571361_43392827_44169746_1_1_1_1,00.html.

VI. References

As indicated under **ADDRESSES**, a docket has been established for this proposed rule under docket ID number EPA-HQ-OPPT-2011-0519. The following is a listing of the documents that are specifically referenced in this action. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting; Revisions to Notification Regulations; Final Rule. **Federal Register** (75 FR 773, January 6, 2010) (FRL-8794-5).

2. EPA. Cross-Media Electronic Reporting; Final Rule. **Federal Register** (70 FR 59848, October 13, 2005) (FRL-7977-1).

3. EPA. TSCA Inventory Update Reporting Rule; Electronic Reporting; Direct Final Rule. **Federal Register** (71 FR 52494, September 6, 2006) (FRL-7752-8).

4. EPA. Inventory Update Reporting Modification; Chemical Data Reporting; Final Rule. **Federal Register** (76 FR 50816, August 16, 2011) (FRL-8872-9).
5. Transfer of Records to the National Archives of the United States. 36 CFR part 1235.
6. EPA. Electronic Toxic Control Act (eTSCA)/e-PMN Reporting Tool User's Guide.
7. EPA. Economic Analysis for Electronic Reporting under TSCA Section 4, Section 5 NOCs, Section 8(a) PAIR, and Section 8(d). February 21, 2012.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866

This action is not a “significant regulatory action” under the terms of Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993), and is therefore not subject to review by the Office of Management and Budget (OMB) under Executive Orders 12866 and 13563, entitled “Improving Regulation and Regulatory Review” (76 FR 3821, January 21, 2011). EPA has prepared an economic analysis of this action, which is contained in a document entitled “Economic Analysis for Electronic Reporting under TSCA Section 4, Section 5 NOCs, Section 8(a) PAIR, and Section 8(d)” (Ref. 7). A copy of the economic analysis is available in the docket for this proposed rule and is summarized in Unit IV.

B. Paperwork Reduction Act

The information collection requirements contained in this proposed rule have been submitted for OMB approval under PRA, 44 U.S.C. 3501 *et seq.* The ICR document prepared by EPA, identified under EPA ICR No. 2412.01 and OMB control number 2070–NEW, is available in the docket for the proposed rule. The ICR addresses the incremental changes to the five currently approved ICR documents that cover the existing reporting and recordkeeping programs that are approved under OMB control numbers 2070-0004, 2070-0012, 2070-0033, 2070-0054,

and 2070-0156. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The amended information collection activities contained in this proposed rule are designed to assist the Agency in meeting its responsibility under TSCA to receive, process, and review reports, data, and other information. As such, responses to the collection of information covered by this ICR would still be mandatory, but with the final rule, respondents would be required to use the CISS reporting tool, except for TSCA section 5 submissions, which would require the use of existing e-PMN software.

Burden is defined at 5 CFR 1320.3(b). The ICR document for this proposed rule provides a detailed presentation of the estimated burden and costs for the first year of the program. The rule-related burden and cost to chemical manufacturers, importers, and processors who would submit notices to the Agency for review is summarized here. The projected total burden to industry is 363 hours per year for the first year of the final rule. This includes an estimated average burden per response of 0.9 hours for CDX registration, 1.8 hours for requesting a CDX electronic signature, and 0.8 hours for final rule familiarization.

Any comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, should be submitted to the docket for this proposed rule, under docket ID number EPA-HQ-OPPT-2011-0519. You may also submit a copy of your comments on the ICR to OMB. See **ADDRESSES** for submission of comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after [*insert date of publication in the Federal Register*], a

comment to OMB is best assured of having its full effect if OMB receives it by [*insert date 30 days after publication in the Federal Register*]. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposed rule.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, the Agency hereby certifies that this proposed rule, if promulgated as proposed, would not have a significant adverse economic impact on a substantial number of small entities.

Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this proposed rule on small entities, small entity is defined as:

1. A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201.
2. A small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000.
3. A small organization that is any not-for-profit enterprise, which is independently owned and operated and is not dominant in its field.

In determining whether a rule has a significant adverse economic impact on a substantial number of small entities, an agency may certify that a rule will not have a significant adverse economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. This proposed rule is expected to reduce the existing regulatory burden. The factual basis for the Agency's certification is presented in the small entity impact analysis prepared as part of the Economic Analysis for this proposed rule, and is briefly summarized in Unit IV. EPA analyzed

reporting data that identified individual companies submitting information under TSCA sections 4, 5, 8(a) PAIR, or 8(d) and identified those companies potentially affected by this proposed rule that qualify for the small business status. EPA estimated the cost impact ratios for small parent entities potentially affected by this proposed rule and has determined that the estimated regulatory costs represent a small impact of less than 1% of their annual revenue. The estimated ratios range from less than 0.0001 % to 0.014 %, depending on the NAICS sector and employment size category, with an average of 0.001 %. No small parent entities are expected to have a cost impact of greater than 1% of annual revenue. Since the estimated regulatory costs represent a small fraction of a typical parent entity's revenue (i.e., less than 1%), the impacts of this proposed rule are likely to be minimal.

D. Unfunded Mandates Reform Act

State, local, and tribal governments have not been affected by the TSCA sections 4, 5, 8(a) PAIR, and 8(d) reporting requirements, and EPA does not have any reason to believe that any State, local, or tribal government would be affected by this proposed rule. Therefore, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

E. Executive Order 13132

Under Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), EPA has determined that this proposed rule would not have federalism implications because the proposed rule would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities

among the various levels of government, as specified in the Executive Order. This proposed rule would establish electronic notification requirements that apply to manufacturers (including importers) and processors of certain chemicals. This proposed rule would not apply directly to States and localities and would not affect State and local governments. Thus, Executive Order 13132 does not apply to this proposed rule.

F. Executive Order 13175

Under Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), EPA has determined that this proposed rule would not have tribal implications because it would not have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in the Executive Order. EPA has no information to indicate that any tribal government manufactures or imports the chemical substances covered by this action. Thus, Executive Order 13175 does not apply to this proposed rule.

G. Executive Order 13045

This proposed rule would not require special consideration pursuant to the terms of Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because this action is not an economically significant action as defined by EO 12866, nor does EPA expect the environmental health or safety risks addressed by this action to present a disproportionate risk to children.

H. Executive Order 13211

This proposed rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May

22, 2001), because this proposal is not an economically significant action as defined by EO 12866, nor would it have any significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), 15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, etc.) that are developed or adopted by voluntary consensus standards bodies. This action is not expected to impose technical standards, and whether an available and applicable voluntary consensus standard needs to be evaluated.

J. Executive Order 12898

This proposed rule does not have an adverse impact on the environmental and health conditions in low-income and minority communities that require special consideration by the Agency under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994). This document proposes to establish procedures for satisfying existing regulatory requirements through electronic reporting. It would not affect the level of protection provided to human health or the environment.

List of Subjects in 40 CFR Parts 712, 716, 720, 721, 723, 725, 766, 790, 799

Environmental protection, Administrative practice and procedure, Business and industry, Chemicals, Reporting and recordkeeping.

Dated: 3/30/12

Louise M. Wise

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 712--[AMENDED]

1. The authority citation for part 712 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

2. In § 712.3, add new paragraphs (q) and (r) to read as follows:

§ 712.3 Definitions.

* * * * *

(q) *Central Data Exchange* or *CDX* means EPA's centralized electronic document receiving system, or its successors.

(r) *Chemical Information Submission System* or *CISS* means EPA's electronic, web-based reporting tool for the completion and submission of data, reports, and other information associated with TSCA sections 4 and 8.

3. In § 712.28, revise paragraphs (c) and (d) and add new paragraph (e) to read as follows:

§ 712.28 Form and instructions.

* * * * *

(c) *Information to be reported.* Persons authorized to report information under this subpart must include the following information on Form 7710-35, Manufacturer's Report--Preliminary Assessment Information (Manufacturer's Report):

(1) A technical certification statement signed and dated by an authorized person located at the plant site or corporate headquarters of the respondent company.

(2) A confidentiality statement signed and dated by an authorized person located at the plant site or corporate headquarters of the respondent company.

(3) The specific chemical name and Chemical Abstracts Service (CAS) Registry Number listed in 40 CFR 712.30.

(4) The name, company, address, city, State, ZIP code, and telephone number of a person who is submitting the form, which may be a person located at a plant site or corporate headquarters that will serve as the respondent, and will be able to answer questions about the information submitted by the company to EPA. A respondent to this subpart must include the appropriate Dun and Bradstreet Number for each plant site reported.

(5) The plant site activities, such as the manufacturing of a chemical substance, including the total quantity of the chemical substance (in kilograms) imported in bulk during the reporting period.

(6) The total number of workers and total worker-hours in each process category, which includes enclosed process, controlled release process, and open process.

(7) The information related to chemical substance processing by customers, including customers' use in industrial and consumer products, the market names under which the chemical substance is manufactured or imported, and the customer's process categories that are sold to customers for further processing.

(d) Persons must use CISS to complete and submit Form 7710-35, Manufacturer's Report, (40 CFR part 712, subpart B) and accompanying letters, via CDX. Submission requires registration with CDX, and must be made only as set forth in this section.

(e) To access CISS go to <https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx> and follow the appropriate links and for further instructions to go <http://www.epa.gov/oppt/chemtest/ereporting/index.html>.

4. In § 712.30, revise paragraphs (a)(3)(i), (a)(3)(ii), and (c)(2) to read as follows:

§ 712.30 Chemical lists and reporting periods.

(a) * * *

(3) * * *

(i)(A) The respondent has previously and voluntarily provided EPA with a Manufacturer's Report on a chemical substance or mixture subject to subpart B of this part, which contains data for a 1-year period ending no more than 3 years prior to the effective date described in paragraph (a)(2) of this section. Respondents meeting this condition must notify EPA by letter of their desire to have the voluntary submission used in lieu of a current data submission and must verify the completeness and current accuracy of the voluntarily submitted data. Such letters, sent in accordance with the method specified in § 712.28(d) to EPA, must contain the following language:

I hereby certify that, to the best of my knowledge and belief, all information entered on this form is complete and accurate. I agree to permit access to, and the copying of records by, a duly authorized representative of the EPA Administrator, in accordance with the Toxic Substances Control Act, to document any information reported on the form.

(B) Notification letters must be submitted in accordance with the method specified in § 712.28(d) prior to the reporting deadline.

(ii) The respondent has previously submitted a Manufacturer's Report on a chemical substance or mixture subject to subpart B of this part to the Interagency Testing Committee, but not to EPA, and that Manufacturer's Report contained data for a 1-year period ending less than 3 years prior to the effective date described in paragraph (a)(2) of this section. Respondents meeting this condition must submit a copy of the Manufacture's Report, in accordance with the method specified in § 712.28(d) to EPA, and must submit an accompanying letter, also in accordance with the methods specified in § 712.28(d), notifying EPA of the respondent's intent

that the submission be used in lieu of a current Manufacturer’s Report. The notification letter must verify the completeness and current accuracy of the voluntarily submitted data.

* * * * *

(c) * * *

(2) You must submit the information using the method specified in § 712.28(d).

* * * * *

Part 716--[AMENDED]

5. The authority citation for part 716 continues to read as follows:

Authority: 15 U.S.C. 2607(d).

6. In § 716.3, add the following definitions in alphabetical order to read as follows:

§ 716.3 Definitions.

* * * * *

Central Data Exchange or *CDX* means EPA’s centralized electronic document receiving system, or its successors.

Chemical Information Submission System or *CISS* means EPA’s electronic, web-based tool for the completion and submission of data, reports, and other information.

* * * * *

7. In § 716.30, revise paragraph (c) and add new paragraph (d) to read as follows:

§ 716.30 Submission of copies of studies.

* * * * *

(c) Persons must use CISS to complete and submit all data, reports, and other information required by 40 CFR part 716, via CDX. Submission requires registration with CDX, and must be made only as set forth in this section.

(d) To access CISS go to

https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx and follow the appropriate links and for further instructions to go *http://www.epa.gov/oppt/chemtest/ereporting/index.html*.

8. In § 716.35, revise paragraph (c) and add new paragraph (d) to read as follows:

§ 716.35 Submission of lists of studies.

* * * * *

(c) Persons must use CISS to complete and submit all data, reports, and other information required by 40 CFR part 716, via CDX. Submission requires registration with CDX, and must be made only as set forth in this section.

(d) To access CISS go to

https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx and follow the appropriate links and for further instructions to go *http://www.epa.gov/oppt/chemtest/ereporting/index.html*.

9. In § 716.40, revise the introductory text of the section to read as follows:

§ 716.40 EPA requests for submission of further information.

EPA may request a person to submit or make available for review the following information after the initial reporting under §§ 716.30 and 716.35. If the requested submissions are not made, EPA may subpoena them under TSCA section 11, 15 U.S.C. 2610.

* * * * *

10. In § 716.55, revise paragraph (b)(3) to read as follows:

§ 716.55 Confidentiality claims.

* * * * *

(b) * * *

(3) Failure to furnish a second copy when information is claimed as confidential in the first copy will be considered a presumptive waiver of the claim of confidentiality. EPA will notify the respondent that a finding of a presumptive waiver of the claim of confidentiality has been made. The respondent will be given 30 days from the date of his or her receipt of this notification to submit the required second copy. If the respondent fails to submit the second copy within the 30 days, EPA will place the first copy in the public docket.

* * * * *

11. In § 716.60, revise paragraphs (a), (b)(2), (c), and (d), and add new paragraph (e) to read as follows:

§ 716.60 Reporting schedule.

(a) *General requirements.* Except as provided in § 716.5 and paragraphs (b) and (c) of this section, submissions under §§ 716.30 and 716.35 must be submitted using the electronic method specified in §§ 716.30(c) and 716.35(d), on or before 60 days after the effective date of the listing of a substance or mixture in § 716.120 or within 60 days of proposing to manufacture (including import) or process a listed substance or listed mixture (including as a known byproduct) if first done after the effective date of the substance or mixture being listed in § 716.120.

(b) * * *

(2) *Submission of copies of completed studies.* Persons must submit studies listed as ongoing or initiated under § 716.35(a)(1) and (a)(2) within 30 days of completing the study, using the method specified in §§ 716.30(c) and 716.35(c).

(c) *Requests for extensions of time.* Respondents who cannot meet a deadline under this section may apply for a reasonable extension of time. Respondents may request an extension

under this section. Extension requests must be submitted on or before 40 days after the effective date of the listing of a substance or mixture in § 716.120, using the electronic method specified in §§ 716.30(c) and 716.35(c). EPA's Director of the Office of Pollution Prevention and Toxics will grant or deny extension requests.

(d) *Submission methods.* Persons must use CISS to complete and submit all data, reports, and other information required by 40 CFR part 716, via CDX. Submission requires registration with CDX, and must be made only as set forth in this section.

(e) To access CISS go to <https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx> and follow the appropriate links and for further instructions to go <http://www.epa.gov/oppt/chemtest/ereporting/index.html>.

12. In § 716.105, revise paragraph (d) and add new paragraph (e) to read as follows:

§ 716.105 Additions of substances and mixtures to which this subpart applies.

* * * * *

(d) Persons who wish to submit information that shows why a substance should be withdrawn must submit their comments by using CISS to complete and submit all data, reports, and other information required by 40 CFR part 716, via CDX. Submission requires registration with CDX, and must be made only as set forth in this section.

(e) To access CISS go to <https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx> and follow the appropriate links and for further instructions to go <http://www.epa.gov/oppt/chemtest/ereporting/index.html>.

Part 720--[AMENDED]

13. The authority citation for part 720 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2613.

14. In § 720.40:

- i. Remove paragraphs (a)(2)(i) and (a)(2)(ii).
- ii. Redesignate paragraphs (a)(2)(iii) and (a)(2)(iv) as paragraphs (a)(2)(i) and (a)(2)(ii).
- iii. Revise newly redesignated paragraph (a)(2)(i).
- iv. Revise paragraph (c).

The amendments read as follows:

§ 720.40 General.

(a) * * *

(2) * * *

(i) *Submission via CDX.* TSCA section 5 notices and any related support documents must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices must be generated and completed on EPA Form 7710-25 using e-PMN software. To obtain a version of e-PMN software that contains an encryption module you must register with CDX. A version without encryption may be downloaded without registering with CDX.

* * * * *

(c) *Where to submit a notice or support documents.* For submitting notices or support documents via CDX, use the e-PMN software.

* * * * *

15. In § 720.75, revise paragraphs (b)(2) and (e)(1) to read as follows:

§ 720.75 Notice review period.

* * * * *

(b) * * *

(2) A request for suspension may only be submitted in a manner set forth in this paragraph. The request for suspension also may be made orally, including by telephone, to the

submitter's EPA contact for that notice, subject to paragraph (b)(3) of this section. Requests for suspension may be submitted electronically to EPA via CDX. Such requests must be generated and completed using e-PMN software. See § 720.40(a)(2)(iv) for information on how to obtain e-PMN software.

* * * * *

(e) *Withdrawal of a notice by the submitter.* (1)(i) A submitter may withdraw a notice during the notice review period by submitting a statement of withdrawal in a manner set forth in this paragraph. The withdrawal is effective upon receipt by EPA of the CDX submission.

(ii) *Submission of withdrawal notices.* EPA will accept statements of withdrawal only if submitted in accordance with this paragraph. Statements of withdrawal must be generated, completed, and submitted to EPA (via CDX) using e-PMN software. See § 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

* * * * *

16. In § 720.102.

- i. Remove paragraph (d)(1).
- ii. Designate the introductory text of paragraph (d) as paragraph (d)(1).
- iii. Revise paragraph (d)(2).

The amendments read as follows:

§ 720.102 Notice of commencement of manufacture or import.

* * * * *

(d) * * *

(2) *Submission of notice of commencement.* EPA will accept notices of commencement only if submitted in accordance with this paragraph. All notices of commencement must be

submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices of commencement must be generated and completed using e-PMN software. See § 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

Part 721--[AMENDED]

17. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

18. In § 721.30, revise paragraph (b) introductory text to read as follows:

§ 721.30 EPA approval of alternative control measures.

* * * * *

(b) Persons submitting a request for a determination of equivalency to EPA under this part must submit the request to EPA via CDX using e-PMN software in the manner set forth in 40 CFR 720.40(a)(2)(i). See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software. Support documents related to these requests must be submitted in the manner set forth in 40 CFR 720.40(c). A request for a determination of equivalency must contain:

* * * * *

19. In § 721.185, revise paragraph (b)(1) to read as follows:

* * * * *

§ 721.185 Limitation or revocation of certain notification requirements.

* * * * *

(b) * * *

(1) Any affected person may request modification or revocation of significant new use notification requirements for a chemical substance that has been added to subpart E of this part using the procedures described in §§ 721.160 or 721.170 by submitting a request that is

accompanied by information sufficient to support the request. Persons submitting a request to EPA under this part must submit the request to EPA using e-PMN software in the manner set forth in 40 CFR 720.40(a)(2)(i). See 40 CFR 720.40(a)(2)(ii) for information on how to obtain the e-PMN software. Support documents related to these requests must also be submitted to EPA in the manner set forth in 40 CFR 720.40(c).

* * * * *

Part 723--[AMENDED]

20. The authority citation for part 723 continues to read as follows:

Authority: 15 U.S.C. 2604.

21. In § 723.50, revise paragraph (e)(1) to read as follows:

§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.

* * * * *

(e) * * *

(1) A manufacturer applying for an exemption under either paragraph (c)(1) or (c)(2) of this section must submit an exemption notice to EPA at least 30 days before manufacture of the new chemical substance begins. Exemption notices and modifications must be submitted to EPA on EPA Form No. 7710-25 via CDX using e-PMN software in the manner set forth in this paragraph. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software. Notices and any related support documents, must be generated and completed (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

* * * * *

Part 725--[AMENDED]

22. The authority citation for part 725 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, 2613, and 2625.

23. In § 725.25, revise paragraph (c) to read as follows:

§ 725.25 General administrative requirements.

* * * * *

(c) *Where to submit information under this part.* MCANs and exemption requests, and any support documents related to these submissions, may only be submitted in a manner set forth in this paragraph. MCANs and exemption requests, and any related support documents, must be generated, completed, and submitted to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

* * * * *

24. In § 725.54, revise paragraphs (b) and (d) to read as follows:

§ 725.54 Suspension of the review period.

* * * * *

(b)(1) *Request for suspension.* A request for suspension may only be submitted in a manner set forth in this paragraph. The request for suspension also may be made orally, including by telephone, to the submitter's EPA contact for that notice, subject to paragraph (c) of this section.

(2) *Submission of suspension notices.* EPA will accept requests for suspension only if submitted in accordance with this paragraph. Requests for suspension, must be generated, completed, and submitted to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

* * * * *

(d) If the submitter has not made a previous oral request, the running of the notice review period is suspended as of the date of receipt of the CDX submission by EPA.

25. In § 725.60, revise paragraph (a) to read as follows:

§ 725.60 Withdrawal of submission by the submitter.

(a)(1) *Withdrawal of notice by the submitter.* A submitter may withdraw a notice during the notice review period by submitting a statement of withdrawal in a manner set forth in this paragraph. The withdrawal is effective upon receipt of the CDX submission by EPA.

(2) *Submission of withdrawal notices.* EPA will accept statements of withdrawal only if submitted in accordance with this paragraph. Statements of withdrawal must be generated, completed, and submitted to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

* * * * *

26. In § 725.190, revise paragraph (d) to read as follows:

§ 725.190 Notice of commencement of manufacture or import.

* * * * *

(d) *How to submit.* All notices of commencement must be generated, completed, and submitted to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

27. In § 725.975, revise paragraph (b) introductory text to read as follows:

§ 725.975 EPA approval of alternative control measures.

* * * * *

(b) Persons submitting a request for a determination of equivalency to EPA under this part must submit the request to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software. Support documents related to these requests must also be submitted to EPA via CDX using e-PMN software. A request for a determination of equivalency must contain:

* * * * *

28. In § 725.984, revise paragraph (b)(1) to read as follows:

§ 725.984 Modification or revocation of certain notification requirements.

* * * * *

(b) * * *

(1) Any affected person may request modification or revocation of significant new use notification requirements for a microorganism that has been added to subpart M of this part using the procedures described in § 725.980. The request must be accompanied by information sufficient to support the request. Persons submitting a request to EPA under this part must submit the request to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software. Support documents related to these requests must also be submitted to EPA via CDX using e-PMN software.

* * * * *

PART 766--[AMENDED]

29. The authority citation for part 766 continues to read as follows:

Authority: 15 U.S.C. 2603 and 2607.

30. In § 766.3, add the following definitions in alphabetical order to read as follows:

§ 766.3 Definitions.

* * * * *

Central Data Exchange or *CDX* means EPA's centralized electronic document receiving system, or its successors.

Chemical Information Submission System or *CISS* means EPA's electronic, web-based reporting tool for the completion and submission of data, reports, and other information.

* * * * *

31. Revise § 766.7 to read as follows:

§ 766.7 Submission of information.

(a) All information (including letters of intent, protocols, data, forms, studies, and allegations) submitted to EPA under this part must bear the applicable Code of Federal Regulations (CFR) section number (e.g., § 766.20) and must be submitted using the method specified in paragraph (b) of this section.

(b) You must use CISS to complete and submit all data, reports, and other information required under this part.

(c) Submissions must be submitted to EPA via CDX.

(d) To access CISS go to

<https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx> and follow the appropriate links and for further instructions to go <http://www.epa.gov/oppt/chemtest/ereporting/index.html>.

PART 790--[AMENDED]

32. The authority citation for part 790 continues to read as follows:

Authority: 15 U.S.C. 2603.

33. In § 790.3, add the following definitions in alphabetical order to read as follows:

§ 790.3 Definitions.

* * * * *

Central Data Exchange or *CDX* means EPA's centralized electronic document receiving system, or its successors.

* * * * *

Chemical Information Submission System or *CISS* means EPA's electronic, web-based tool for the completion and submission of data, reports, and other information.

* * * * *

34. Revise § 790.5 to read as follows:

§ 790.5 Submission of information.

(a) All submissions and correspondence to EPA under this part must bear the Code of Federal Regulations (CFR) section number of the subject chemical test rule or, for the consent agreements.

(b) You must use CISS to complete and submit via CDX all data, reports, other information, and correspondence required by rules promulgated under TSCA section 4, and for correspondence pertaining to consent agreements as required under this part. The submissions must be made only as set forth in this section.

(c) To access CISS go to

<https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx> and follow the appropriate links and for further instructions to go <http://www.epa.gov/oppt/chemtest/ereporting/index.html>.

35. In § 790.45, revise paragraph (a) to read as follows:

§ 790.45 Submission of letter of intent to conduct testing or exemption application.

(a) No later than 30 days after the effective date of a test rule described in § 790.40, each person subject to that test rule and required to comply with the requirements of that test rule as

provided in § 790.42(a) must, for each test required, send his or her notice of intent to conduct testing, or submit to EPA an application for exemption from testing by the method specified in § 790.5(b).

* * * * *

36. In § 790.48, revise paragraphs (a)(2), (a)(3), (b)(3), (b)(4), (b)(5), (c)(2), and (c)(3) to read as follows:

§ 790.48 Procedure if no one submits a letter of intent to conduct testing.

(a) * * *

(2) If no manufacturer subject to the test rule has notified EPA of its intent to conduct one or more of the required tests within 30 days after the effective date of the test rule described in § 790.40, EPA will notify all manufacturers, including those described in § 790.42(a)(4) and (a)(5), through CDX or by publishing a notice of this fact in the **Federal Register** specifying the tests for which no letter of intent has been submitted and will give such manufacturers an opportunity to take corrective action.

(3) If no manufacturer submits a letter of intent to conduct one or more of the required tests within 30 days after receipt of EPA's notification under paragraph (a)(2) of this section, all manufacturers subject to the test rule will be in violation of the test rule from the 31st day after receipt of the submission or publication of the **Federal Register** notice described in paragraph (a)(2) of this section.

(b) * * *

(3) No later than 30 days after the date of publication of the **Federal Register** notice described in paragraph (b)(2) of this section, each person described in § 790.40(a)(4) and (a)(5) and each person processing the subject chemical as of the effective date of the test rule described

in § 790.40 or by 30 days after the date of publication of the **Federal Register** notice described in paragraph (b)(2) of this section must, for each test specified in the **Federal Register** notice, either notify EPA of his or her intent to conduct testing, or submit to EPA an application for an exemption from testing requirements for the test. Each such notification to conduct testing or application for exemption from testing must be submitted to EPA by the method specified in § 790.5(b).

(4) If no manufacturer or processor of the test chemical has submitted a letter of intent to conduct one or more of the required tests within 30 days after the date of publication of the **Federal Register** notice described in paragraph (b)(2) of this section, EPA will notify all manufacturers and processors through CDX or publish a **Federal Register** notice of this fact specifying the tests for which no letter of intent has been submitted. The CDX notification or **Federal Register** notice will give the manufacturers and processors an opportunity to take corrective action.

(5) If no manufacturer or processor submits a letter of intent to EPA through CDX within 30 days after either receipt of the CDX notification from EPA under paragraph (b)(4) of this section, all manufacturers and processors subject to the test rule will be in violation of the test rule from the 31st day after receipt of such notification or publication of the **Federal Register** notice.

(c) * * *

(2) If no processor subject to the test rule has notified EPA through CDX of its intent to conduct one or more of the required tests within 30 days after the effective date of the test rule described in § 790.40, EPA will notify all the processors through CDX or publish a notice in the

Federal Register of this fact, specifying the tests for which no letter of intent has been submitted and to give the processors an opportunity to take corrective action.

(3) If no processor submits a letter of intent through CDX to conduct one or more of the required tests within 30 days after receipt of the Agency's notification under paragraph (c)(2) of this section, all processors subject to the test rule will be in violation of the test rule from the 31st day after receipt of the CDX notification or publication of the **Federal Register** notice described in paragraph (c)(2) of this section.

37. In § 790.50, revise paragraphs (b)(1), (b)(3), and (e) to read as follows:

§ 790.50 Submission of study plans.

* * * * *

(b) * * *

(1) EPA may grant requests for additional time for the development of study plans on a case-by-case basis. Requests for additional time for study plan development must be submitted to EPA by the method specified in § 790.5(b). Any extension request must state why EPA should grant the extension.

* * * * *

(3) EPA will notify the submitter of EPA's decision to grant or deny an extension request through CDX.

* * * * *

(e) *Amendments to study plans.* Test sponsors must submit all amendments by the method specified in § 790.5(b).

38. In § 790.55, revise paragraphs (a) and (b)(2) to read as follows:

§ 790.55 Modification of test standards or schedules during conduct of test.

(a) *Application.* Any test sponsor who wishes to modify the test schedule for the mandatory testing conditions or requirements (i.e., “shall statements”) in the test standard for any test required by a test rule must submit an application in accordance with this paragraph. Application for modification must be made by the method specified in § 790.5(b). Applications must include an appropriate explanation and rationale for the modification. Where a test sponsor requests EPA to provide guidance or to clarify a non-mandatory testing requirement (i.e., “should statements”) in a test standard, the test sponsor must submit these requests to EPA by the method format specified in § 790.5(b).

(b) * * *

(2) Where, in EPA's judgment, the requested modification of the test standard or schedule would not alter the scope of the test or significantly change the schedule for completing the test, EPA will not ask for public comment before approving the modification. EPA will notify the test sponsor of EPA's decision via CDX. EPA will place copies of each application and EPA approval notification in the docket for the test rule in question. EPA will publish a notice annually in the **Federal Register** indicating the test standards or schedules for tests required in test rules which have been modified under this paragraph (b)(2) and describing the nature of the modifications. Until the **Federal Register** notice is published, any modification approved by EPA under paragraph (b)(2) of this section shall apply only to the test sponsor who applied for the modification under paragraph (a) of this section.

* * * * *

39. In § 790.62, revise paragraph (c)(4) to read as follows:

§ 790.62 Submission of study plans and conduct of testing.

* * * * *

(c) * * *

(4) The test sponsor shall submit any amendments to study plans to EPA using the method specified in § 790.5(b).

* * * * *

40. In § 790.68, revise paragraphs (b)(1) and (b)(2)(ii) to read as follows:

§ 790.68 Modification of consent agreements.

* * * * *

(b) * * *

(1) Any test sponsor who wishes to modify the test schedule for any test required under a consent agreement must submit an application in accordance with this paragraph. Application for modification must be made using the method specified in § 790.5(b). Applications must include an appropriate explanation and rationale for the modification. EPA will consider only those applications that request modifications to mandatory testing conditions or requirements (“shall statements” in the consent agreement). Where a test sponsor requests EPA to provide guidance or to clarify a non-mandatory testing requirement (i.e., “should statements”), the test sponsor shall submit these requests to EPA using the method specified in § 790.5(b).

(2) * * *

(ii) Where, in EPA's judgment, the requested modification of a test standard or schedule would not alter the scope of the test or significantly change the schedule for completing the test, EPA will not ask for public comment before approving the modification. EPA will notify the test sponsor and any other persons who have signed the consent agreement through CDX of EPA's approval. EPA will place copies of each application and EPA approval notification in the docket maintained for the consent agreement in question. EPA will publish a notice annually in the

Federal Register indicating the test standards or schedules for test required in consent agreements which have been modified under paragraph (b)(2)(ii) of this section and describing the nature of the modifications.

* * * * *

41. In § 790.87, revise paragraphs (b)(2)(i), (b)(2)(ii), and (c) to read as follows:

§ 790.87 Approval of exemption applications.

* * * * *

(b) * * *

(2) * * *

(i) If EPA finds an equivalence claim to be in error or inadequately supported, the applicant will be notified through CDX. The applicant will be given 15 days to provide clarifying information.

(ii) Exemption applicants will be notified through CDX that equivalence has been accepted or rejected.

(c)(1) EPA will give exemption applicants final notice that they have received a conditional exemption through one of the following ways:

(i) A final Phase II test rule that adopts the study plans in a two-phase rulemaking.

(ii) A separate **Federal Register** notice in a single-phase rulemaking.

(iii) CDX.

(2) All conditional exemptions thus granted are contingent upon the test sponsors' successful completion of testing according to the specifications of the test rule.

42. In § 790.88, revise paragraph (b) to read as follows:

§ 790.88 Denial of exemption application.

* * * * *

(b) EPA will notify the exemption applicant through CDX or by a **Federal Register** notice of EPA's determination that the exemption application is denied.

43. In § 790.90, revise paragraph (c)(2) to read as follows:

§ 790.90 Appeal of denial of exemption application.

* * * * *

(c) * * *

(2) Hearing requests must be submitted using the method specified in § 790.5(b) and be received by EPA within 30 days of receipt of the Agency's notification under § 790.88(b).

Hearing requests must provide reasons why a hearing is necessary.

* * * * *

44. In § 790.93, revise paragraphs (b), (c), (d)(2), and (e) to read as follows:

§ 790.93 Termination of conditional exemption.

* * * * *

(b) If EPA determines that one or more of the criteria listed in paragraph (a) of this section has been met, EPA will notify each holder of an affected conditional exemption through CDX or a **Federal Register** notice of EPA's intent to terminate that conditional exemption.

(c) Within 30 days after receipt of notification under paragraph (b) of this section that EPA intends to terminate a conditional exemption, the exemption holder may submit information using the method specified in § 790.5(b) either to rebut EPA's preliminary decision or notify EPA of its intent to conduct the required test pursuant to the test standard established in the test rule. Such a letter of intent shall contain all of the information required by § 790.45(c).

(d) * * *

(2) Hearing requests must be submitted using the method specified in § 790.5(b) and must be received by EPA within 30 days after receipt of the CDX notification or after publication of a notice in the **Federal Register** as described in paragraph (b) of this section.

(e) EPA will notify the exemption holder through CDX or by **Federal Register** notice of EPA's final decision concerning termination of conditional exemptions and will give instructions as to what actions the former exemption holder must take to avoid being found in violation of the test rule.

45. In § 790.97, revise paragraphs (a) and (c) to read as follows:

§ 790.97 Hearing procedures.

(a) Hearing requests must be submitted using the method specified in § 790.5(b). Such requests must include the applicant's basis for appealing EPA's decision.

* * * * *

(c) EPA will notify each applicant of EPA's decision through CDX within 60 days after the hearing.

PART 799--[AMENDED]

46. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, and 2625.

47. Revise § 799.5 to read as follows:

§ 799.5 Submission of information.

(a) Information (e.g., letters, study plans, or reports) submitted to EPA must be submitted using the method specified in paragraph (b) of this section. All information submitted under this

part must bear the Code of Federal Regulations (CFR) section number of the subject chemical test rule (e.g., § 799.1053 for trichlorobenzenes).

(b) You must use CISS to complete and submit all data, reports, and other information required under this part. Submissions must be submitted to EPA via CDX.

(c) To access CISS go to

<https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx> and follow the appropriate links and for further instructions to go *<http://www.epa.gov/oppt/chemtest/ereporting/index.html>*.